Local Posting NCTR-2024-120916

5/14/24

The FDA has a requirement for Litron In-Vitro Micro Flow Assay Kits, quantity of 6.

Sole Source Justification: The U.S. Food and Drug Administration (FDA)/National Center for Toxicological Research (NCTR) intends to award a sole source, firm fixed price purchase order to Litron Laboratories, 3500 Winton Place, Rochester, NY 14623, under the authority of FAR 13.106-1(b)(1), Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements.

The Food and Drug Administration (FDA)/National Center for Toxicological Research (NCTR) NCTR requires six In-vitro microflow assay kits, which will be used for MN data collections in support of NCTR protocol E07817.01. The laboratory has used the Litron In vitro-1,000/200 Microflow assay kit for more than a decade to assess the genotoxicity of various chemicals or chemical mixtures in several protocols E750101, E760901, E773701, E07791.01 and S00904.

Litron Laboratories is the owner and manufacturer of the assay kits. Litron Labs is the only known seller of the kits; there are no known third-party resellers. Data generated from these projects have been used to support other FDA product centers for regulatory decision-making and published in peer-reviewed journals. Acquisition of these kits is essential for the continuity of the data collection; past, present, and future. Attempting to introduce another vendor at this time could impact the entire research program. In an effort to maintain continuity and consistency, FDA/NCTR will purchase the kits from Litron Labs.

For more information regarding this requirement please contact Nick Sartain at 870-543-7370 or email at nick.sartain@fda.hhs.gov. All applicable FAR and HHSAR Clauses will be included in any resultant award.

All responsible sources may submit a response which, if timely received, must be considered by the agency. Responses due by 1:00 PM Central Time on 5/17/2024.